

REMARKS

There are two rejections in the existing Office Action to this application. These rejections are premised under 35 U.S.C. §112, first paragraph and under 35 U.S.C. §112, second paragraph. However, both rejections are premised upon the same objection. The objection is that the term "S-30 extract" lacks sufficient definiteness. In the 112, first paragraph, rejection the Examiner contends that the use of the term "S-30 extract" in the specification renders that specification non-enabling, and therefore insufficient, because the specification fails to specify the materials which make up the S-30 extract. In the rejection under §112, second paragraph, the Examiner rejects the claims of this application on the grounds that use of the term "S-30 extract" does not specify sufficient information as to the scope of what such an extract is.

The applicants respectfully disagree with the Examiner and traverses this requirement. While the term "extract" in and of itself may lack definiteness under some circumstances, the term "S-30 extract" is a well known and often used term of the art in the art to which this invention pertains. The art to which this invention pertains is the design and execution of systems for *in vitro* transcription and translation of genes to make proteins. In that art, the term "S-30 extract" has a well and clear defined meaning that is well recognized by the art and commonly used by the workers in that field. Accordingly, since the applicants are fully entitled to use words in the specification that are known to those of ordinary skill in the art, there is no uncertainty or indefiniteness whatsoever in using this term.

The Examiner has concluded that the term "S-30 extract" is indefinite only by refusing to consider the material already in the record in this patent application. First, as clearly explained in the specification, in the sentence bridging pages 1 and 2, the use of the term S-30 extract has a clear and defining inception date. It was first used in a paper by Zubay which appeared in the *Annual Review of Genetics* in 1973. A copy of that paper was supplied to the Examiner in conjunction with the IDS submitted by the applicants. In that paper, the term "S-30 extract" is repeatedly used to refer to a specific extract of materials from bacterial cells. The paper then goes on to describe applications and uses for this type of extract.

At the time of filing this patent application, investigators could obtain S-30 extracts in either of two ways. An investigator could simply make such an extract using the procedures described in, among others, the Zubay paper. Alternatively, the investigator could simply buy an aliquot of S-30 extract, sold under that name, from the reagent supply companies. Also included with the IDS in this case were copies of literature describing commercial S-30

extract from Promega and Ambion, which were commercially available before the filing of this patent application. The market has clearly acknowledged certainty as to what an S-30 extract is, since both companies specifically describe their products to their customers using that term.

The applicants have already supplied to the investigator copies of a number of prior art scientific papers which explicitly use the term S-30 extract to define the materials made by the process described in the Zubay paper.

Thus, the applicants supplied to the Examiner clear examples of prior art references which use the term "S-30 extract" specifically in that same meaning that it is used in this patent application. It is worthy of note in this regard that although the applicants have submitted a Form 1449 (filed October 2, 2001), the Examiner has not acknowledged that document or cited any of the documents supplied to the Examiner therewith. Note that several of the papers refer to the use of an S-30 extract in their very title. For example the papers to Kang, Lesley, and three Promega Technical Bulletins, copies of all of which have been supplied to the Examiner, use the term "S-30 extract" in their titles.

The present patent application is assigned to a copy known as Novagen, Inc., now a part of BMD Biosciences. Novagen offers a product made in accordance with the present invention under the trademark EcoPro. In addition to Novagen, three other manufacturers offer continue to sell cell free prokaryotic transcription and translation products for sale to the research community. All refer to these products as S-30 extracts. Those companies are Promega, Ambion, and Invitrogen. Description of the Promega product can be found at the following web site: <http://www.promega.com/tbs/tb102/tb102.ntml>. The product offered by Ambion is described at the following web site:

http://www.ambion.com/techlib/prot/bp_1290.pdf. The product offered by Invitrogen is described at the following web site: <http://www.invitrogen.com/content.cfm?pageid=9482>.

A paper describing the relative comparison of the results obtained using the process of the present invention (referred to as EcoPro) as compared to prior S-30 products can be found at the applicants' web site at:

http://www.novagen.com/SharedImages/TechnicalLiterature/7_nllc.pdf.

Any even cursory review of the scientific literature will reveal that the term S-30 extract is widely used in the literature to refer to a cellular extract which is exactly the same extract referred to by the applicants here. At the Scirus web site, which can be found at the URL: <http://www.scirus.com/>, a search for exact term "S30 extract" yielded 104 mentions in scientific journals and 132 mentions at web sites, and a search for "S-30 extract" yields

another 40 papers and 9 websites. (The terms S-30 extract and S30 extract are used to describe the same material). Similarly, a search of the publication index at the National Library of Medicine, which can be found at the URL <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=Search&BD=PubMed>, reveals another 40 papers uncovered using the search term S30 extract and another 28 using the term S-30 extract. The web even contains a buyer's guide which compares various extract products, referred to some of them clearly as S30 extracts, as they might be of use by the research community. This guide can be found at <http://www.biocompare.com/molbio.asp?catid=823>.

What follows next is a list of additional URLs, each of which refers to papers which can be conveniently found in the web, and each of which specifically references a cellular extract product by the name "S30 extract" or "S-30 extract."

<http://www.unizh.ch/~pluckth/publications/pdf/APpub0198.pdf>,
http://216.239.33.104/search?q=cache:ruJFcg3kTC8C:www.nature.com/cgi-taf/DynaPage.taf%3Ffile%3D/nbt/journal/v19/n8/full/nbt0801_751.html+S30+extract&hl=en&ie=UTF-8,
http://www.nature.com/ncb/journal/v4/n6/fig_tab/ncb795_F5.html,
<http://www.icmask.org/icmasko5/poster/2.04.pdf>,
<http://www.bact.wisc.edu/biotech/gradstudents/JulieDavis/Profile.htm>,
<http://www.su.se/forskning/disputationer/spikblad/RichardOdegrip.html>,
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10731664&dopt=Abstract,
<http://bletchley.tamu.edu/homepage/pdf/biophys76-1999.pdf>,
<http://www.mit.edu:8001/people/gyjung/Cell.htm>.

On the PTO's own web site, a search of issued patents revealed 134 patents using the term "S30 extract" and another 11 issued patents using the term "S-30 extract."

The core requirement on the applicants here is to enable the invention and define the invention. On the issue of enablement, the Examiner has provided no logic or reasoning why the use of the term S-30 extract, other than the admitted fact that the phrase includes the word "extract." The fact that the phrase "S-30 (or S30) extract" is well known and used in the art to refer to a well characterized product, and a commercial product at that, has not been considered by the Examiner. The Examiner would require to the applicants to "give the exact structure of the extract or ingredients in the extract" before an appropriate search can be conducted. This assertion is wrong as matter of law, and as a matter of fact.

It is a requirement that the applicants define a product as completely as possible. However, it is impossible with precision to define all of the components in a material which was made from living cells. The exact manifest of all of the molecules which exist in a living cell is not yet known. As is clearly recited in the specification, and can be seen with reference to the Zubay paper, the S-30 extract, as it is known in the art, is a product which is the result of a certain processing of prokaryotic cells. That processing results in an extract which contains the transcriptional and translational materials of the cells, isolated from other cellular components. This process is well understood in the technology commonly used in research labs all across the country, and taught in molecular biology courses around the United States and around the world. The resulting product is used widely in the research community and sold to that community under this name. The material is defined to the extent it is possible to define the material given the present state of human knowledge. The PTO permits claims to cells and organisms, which are complex mixtures of ingredients. There is no expressed reasoning as to why a higher standard should be applied to the subject matter of the applicants here.

Secondly, as a matter of act, the subject matter of this patent application is easily searchable, since the term S-30 (or S30) extract is commonly used for this material, as shown by the search results cited above.

Note that while the applicant in a patent application is permitted to be his own lexicographer, the applicants have not done that here. The applicants have used a term in the art to refer to a cellular product, by the term in which that product is commonly known throughout the industry and the literature. The Examiner has taken the fact that the name of this byproduct includes the word "extract" and implied from that that somehow this extract is indefinite in its content. The contrary is true. The extract has is a mixture made by a defined process. The world understands how to make such an extract and use it. The literature is replete with examples of it, as referenced above. There is no uncertainty about what an S-30 extract is.

The applicants have clearly described in its specification how a "conventional" S-30 extract may be manipulated by the processes described by the applicants here to create a variant that has improved properties and results. The applicants have characterized both the processes by which that improved extract can be made from a conventional S-30 extract and also has defined, to the extent it knows it, the characteristics of the improved extract which differ from a conventional S-30 extract. The application is thus enabling for exactly the

process the applicants have described and the products the applicants claim have been defined to the extent possible.

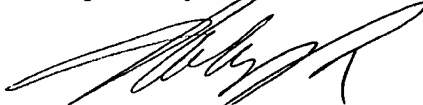
Clearly the process for making the improved S-30 extract described and claimed in this patent application was enabled in fact by this specification. In fact, in its most simplistic embodiment, the improved S-30 extract described here can be made by taking a conventional S-30 extract, freezing it, thawing it, and then simply centrifuging and decanting it to make the material clear. This is recited in the specification, paragraph 27. Since S-30 extracts were readily commercially available at the time this application was filed, and minimally competent scientist could perform this invention without any difficulty. The Examiner has provided no reasoning why there is any such difficulty. The case for non-enablement has not been made by the Examiner.

Again, while the applicants have correctly noted that in other context, the term "extract" in and by itself might be indefinite, that is not the case here. The combined term "S-30 extract" has a clear meaning in the art, is commonly used in the technology, and is widely referred to in the industry referring to a specific product. There is no indefiniteness in the use of that term. The Examiner is required to acknowledge and comply with uses of terminology used by one of ordinary skill in the art to which the invention pertains. In the art of *in vitro* transcription and translation, the area to which this invention pertains, the term "S-30 extract" has a clear, definite, and well understood meaning. The Examiner could exhaustively search this art, using this term, if the Examiner was so inclined.

Wherefore the rejections applied by the Examiner against this patent application are respectfully traversed. Reconsideration of the merits of this patent application is respectfully requested.

A separate petition for extension of time is submitted so that this response will be considered as timely filed.

Respectfully submitted,



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